



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

MAR 18 1999

De Lois L. Shelton
Regulatory Compliance
Weider Nutrition International, Inc.
2002 South 5070 West
Salt Lake City, Utah 84104-4836

Dear Ms. Shelton:

This is in response to your letter of February 10, 1999, to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Weider Nutrition International, Inc. is making the following claim for the product **Sinus Free™ Two Phase System**:

"Sinus Free™ provides the nutritional support your body needs during allergy season. This unique two phase system helps your body stay healthy even when exposed to foreign elements."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to treat, prevent, or mitigate a disease, namely, allergies. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

97S-0163

LET 268

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Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Denver District Office, Office of Compliance, HFR-SW240

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (file, r/f)

HFS-450 (r/f, file)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-605 (Bowers)

HFV-228 (Benz)

HFV-232 (Brown)

GCF-1 (Nickerson, Dorsey)

r/d:HFS-456:RMoore:2/24/99

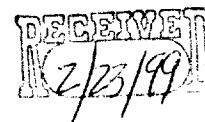
Init:GCF-1:DDorsey:3/16/99

f/t:HFS-456:rjm:3/17/99:docname:63818.adv:disc36

NOTIFICATION PURSUANT TO
SECTION 6 OF DSHEA

In compliance with Section 6 of the Dietary Supplement Health Education Act (DSHEA) and Rule 21 C.F.R. 101.93, this Notification is filed on behalf of the following manufacturer of **Schiff® Sinus Free™ Two Phase System (24 lozenges & 10 capsules) Product #12201** bearing the statements set out below:

Weider Nutrition International., Inc.
2002 South 5070 West
Salt Lake City, Utah 84104



The text of each structure-function claim for **Zinc, Zhi Shi, Tylophlora indica / asthmatica & Adhatoda vasica** is as follows:

- (Statement 1) Zinc Lozenges to support a normal immune system.
- (Statement 2) Herbal Capsules to promote a healthy respiratory system.
- (Statement 3) **Sinus Free™** provides the nutritional support your body needs during the allergy season. This unique two phase system helps your body stay healthy even when exposed to foreign elements.

I, Luke R. Bucci, Ph.D., CCN, CNS, Vice President of Research at Weider Nutrition International., Inc. am authorized to certify this Notification of behalf of the Company. I certify that the information presented and contained in this Notification is complete and accurate and that the Office of Regulatory Affairs at Weider Nutrition International, Inc. has substantiation that each statement is truthful and not misleading.

DATED this 12th day of February, 199 9.

WEIDER NUTRITION INTERNATIONAL, INC.

BY: CSR Bucci
DR. LUKE R. BUCCI
Vice President of Research

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